Remarks/Arguments

Claims 1-66 are pending. Claims 61-65 have been withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1-60 and 66 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,772,473 in view of U.S. Patent Publication No. 2003/0180359 or U.S. Patent No. 4,792,452 and U.S. Patent No. 5,415,871.

The '473 patent teaches a combined sustained/rapid release nitrofurantoin capsule including the sustained release excipients polyvinylpyrrolidone (PVP) and carboxyvinyl polymer. According to the Examiner, the '473 patent discloses all the limitations of the instant claims except for the first component controlled release excipients (sodium alginate, alginic acid, hypromellose). Office Action, p. 3.

The Examiner contends that the '359 publication discloses multi-layer dosage forms comprising an active layer including PVP, HPMC (hypromellose), carboxyvinyl polymers, alginic acid and derivatives such as sodium alginate.

According to the Examiner, the '452 patent: "teaches a controlled release formulation comprising a pharmaceutical and polymers of alginic acid such as sodium alginate and HPMC … [and] that mixtures of the same or different alginic acid derivatives can be used." Office Action, p. 5. The Examiner contends that the '871 patent "teaches that polymer having sustained release properties include sodium alginate or alginic acid and HPMC." *Id.*

According to the Examiner, a skilled artisan would know how to substitute the sustained release polymers of '359 or '452 and '871 for the polymers in the '473 product. Further, the Examiner contends that adjusting the percent of a compound in a formulation is a matter of simple optimization. Office Action, p. 6.

Applicants respectfully traverse this rejection.

The '473 patent states that: "polyvinylpyrrolidone is a necessary ingredient to achieve sustained release of the nitrofurantoin." '473 patent, col. 6, ll. 37-39. Thus, the '473 patent one of ordinary skill in the art would not have replaced the sustained release excipient PVP with the

instantly claimed excipients, or any other excipient, because to do so would omit a "necessary ingredient" to achieve sustained release of nitrofurantoin.

Further, the '473 patent states that: "[c]arboxyvinylpolymer is another necessary ingredient in order to achieve the sustained release pharmaceutical capsules of the present invention." '473 patent, col. 7, ll. 18-20. Thus, the '473 patent one of ordinary skill in the art would not have replaced the sustained release excipient carboxyvinylpolymer with the instantly claimed excipients, or any other excipient, because to do so would omit a "necessary ingredient" to achieve sustained release of nitrofurantoin.

The '359 publication , '452 patent, and '871 patent do not disclose nitrofurantoin. These references do not disclose or suggest any reason to contradict the express teaching of the '473 patent that PVP and carboxyvinylpolymer are necessary to achieve sustained release of nitrofurantoin, and instead employ the instantly claimed excipients. Accordingly, no combination of the references discloses or suggests the instantly claimed formulation, and this rejection should be withdrawn.

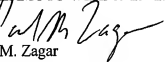
Conclusion

This application is believed to be in condition for allowance. If any issues remain that can be addressed by a supplemental or Examiner's amendment, the Examiner is respectfully requested to contact the undersigned.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Paul M. Zagar
Registration No. 52,392

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 212.547.5400
Facsimile: 202.756.8087
Date: January 15, 2010

Please recognize our Customer No. 20277 as our correspondence address.